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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,550	06/28/2001	Albert Collinson	BBC-083 A US	6240

7590 12/09/2004

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EXAMINER
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ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Interview Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/894,550	COLLINSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Janet L. Andres	1646	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Janet L. Andres. (3) Kenneth Zwicker.  
 (2) Deborah Reynolds. (4) \_\_\_\_\_.

Date of Interview: 02 December 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference  
 c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.  
 If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: pending claims.

Identification of prior art discussed: Lugar.


Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
 Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant's representative stated that the generation of a dual specificity antibody, as opposed to a bi-specific antibody, was not generally contemplated in the art. Applicant's representative stated that Lugar provides no motivation to generate not-fully mouse versions of the antibody described by Lugar and that Lugar merely states that the antibody could be used in assays. Applicant's representative stated that Lugar did not suggest a therapeutic use or suggest that the antibody be rendered not fully mouse. With respect to the rejection of the claims as lacking enablement commensurate with their scope, Applicant's representative stated that Applicant's disclosure of non-working embodiments was held against Applicant, and further requested clarification as to how many successes need be described for the invention to be considered to be fully enabled. Examiner Andres stated that Lugar in fact taught an antibody with the desired binding characteristics and what was required was motivation to humanize or otherwise alter it. It was the Examiners' position that interleukin 1 is a well known pro-inflammatory molecule and it would be obvious to the artisan to generate a therapeutically useful antibody. It was also the Examiners' position that Lugar need not state that it would be advantageous to use the antibody therapeutically and to generate not fully mouse versions; since the role of interleukin 1 was not only stated by Lugar, but well known in the art, as was the optimization of antibodies for therapeutic use. With respect to the enablement issue, it was the Examiners' position that Applicant had not described the genus of epitopes needed to generate dual specificity antibodies since neither relevant characteristics nor a sufficient number of embodiments were provided; Applicant has disclosed only one that can be used. It was explained by BPS Reynolds that there was no set rule for the number of embodiments that need be disclosed; what is required is sufficient information to describe the genus that must be used

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	Janet L. Andres		1646	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Janet L. Andres. (3) Kenneth Zwicker.  
 (2) Brenda Brumback. (4) Tara Seshadri.

Date of Interview: 18 October 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference  
 c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.  
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Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant's representative stated that the rejection of the claims under 35 U.S.C. 103 was improper because there was no motivation to humanize the antibody of Lugar and further no motivation to generate a dual specificity antibody. Applicant's representative further stated that extensive experimentation to generate antibodies is routine in the art and that Applicant's disclosure of non-working embodiments was held against Applicant. The Examiners' position was that the antibody taught by Lugar inhibits the activity of a known pro-inflammatory agent, interleukin 1, and that it would be obvious to the artisan to humanize the antibody for therapeutic use. Examiner Andes also stated that no motivation was required to produce a dual specificity antibody, since Lugar had already done so. With respect to enablement, Examiner Andres explained that of the four peptides used in an attempt to generate an antibody with the desired properties, three had failed, and thus Applicant was not in possession of the epitopes needed to produce the antibodies as broadly claimed.